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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,484	04/25/2001	Paul L. DeAngelis	4605.003	2281

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EXAMINER

HENRY, MICHAEL C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/842,484

Applicant(s)

DEANGELIS, PAUL L.

Examiner

Michael C. Henry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 37-44, 97-106 and 110-130 is/are pending in the application.
- 4a) Of the above claim(s) 97-106, 110 and 126 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-44, 111-125 and 127-130 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The following office action is a responsive to the Amendment filed, 03/17/04.

The amendment filed 03/17/04 affects the application, 09/842,484 as follows:

1. Claims 42-44, 111-125,127 have been amended. Claims 1-36, 45-96 and 107-109 have been cancelled. Claims 97-106, 110 and 126 have been withdrawn. This leaves claims 37-44, 111-125 and 127-130.

2. Applicant responds to the rejection under 35 USC 103 by amending claim 1.

The responsive to applicants' arguments is contained herein below.

Claims 37-44, 111-125, 127-130, 97-106, 110 and 126 are pending in application

#### *Claim Objections*

Claims 42-44 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 42-44 **not been further** treated on the merits.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37-41 and 128-130 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugumaran et al. (Journal of Biological Chemistry, (1997 May 30) 272 (22) 14399-403). Claim 37 is a product-by-process claim, wherein applicant claims "A purified composition, wherein the

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purified composition comprises a chondroitin polymer made by a recombinant process.”

Sugumaran et al. disclose applicant’s purified composition, wherein the purified composition comprises a chondroitin polymer (see abstract; see 1st col., 2<sup>nd</sup> paragraph, page 14400). A quotation from the MPEP (Manual of Patent Examining Procedure, 8 ed., August 2001) pertaining to Product-by-Process Claims is given below in order to further corroborate the reason for the aforementioned rejection. The quotation states that “PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).” It should be noted that claims 38-41 and 128-130 which are drawn to chondroitin polymer or a composition comprising chondroitin polymer are also product-by-process claims which are also anticipated by Sugumaran et al.

Claims 37-41, 111-125 and 127-130 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakanishi et al. (The Journal of biological Chemistry 1981, 256 (11) 5443-5449). Claim 37 is a product-by-process claim, wherein applicant claims “A purified composition, wherein the purified composition comprises a chondroitin polymer made by a recombinant process.” Sugumaran et al. disclose applicant’s purified composition, wherein the purified composition comprises a chondroitin polymer (abstract and page 5444, lines 1-3). A quotation from the MPEP (Manual of Patent Examining Procedure, 8 ed., August 2001) pertaining to Product-by-Process Claims is given below in order to further corroborate the reason for the

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aforementioned rejection. The quotation states that "PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)." It should be noted that claims 37-41, 111-125, and 127-130 which are drawn to unsulfated chondroitin polymer or chondroitin polymer or a composition comprising unsulfated chondroitin polymer or chondroitin polymer, are also product-by-process claims which are also anticipated by Nakanishi et al.

***Response to Amendment***

Applicant's arguments with respect to claims 37-44, 111-125 and 127-130 have been considered but are not found convincing.

The applicant argues that the Sugumaran et al. reference does not describe, identify, or even suggest a recombinantly produced, unsulfated chondroitin polymer and the enzyme (and methodology) that makes the unsulfated chondroitin polymer chains (i.e. chondroitin synthase). However, the applicant chondroitin polymer as claimed is anticipated by Sugumaran et al. As claimed, there is no difference between Sugumaran et al.'s chondroitin polymer and applicant's. The chondroitin polymer as claimed is the same as Sugumaran et al. and consequently the process by which applicant's chondroitin polymer is prepared does not render their said chondroitin polymer as being different from Sugumaran et al.'s chondroitin polymer.

Applicant's arguments with respect to claims 54 and 59 have been considered but are not found convincing.

The applicant argues that chondroitin-based starting materials used by Casu et al. were not unsulfated chondroitin. However, applicant claims chondroitin not unsulfated chondroitin in the previously examined claims for which the said reference was applied.

The applicant argues that the Skjak-Braek et al. reference teaches a sulfated chondroitin. However, applicant claims chondroitin not unsulfated chondroitin in the previously examined claims for which the said reference was applied.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the


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examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

July 13, 2004.



JAMES O. WILSON  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600